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Improving Shared Decision-Making in Early Phase Clinical Trials and Palliative Care: A Prospective Study on the Impact of an Online Value Clarification Tool Intervention

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Keywords: cancer | decisional conflict | early phase clinical trials | oncology | online tool | patient-provider communication | shared decision-making | value clarification

ABSTRACT

Objectives: This study evaluated the impact of the OnVaCT intervention, a narrative-based Online Value Clarification Tool (OnVaCT), combined with communication training for oncologists, on shared decision-making (SDM) in discussions on potential early phase clinical trial participation and palliative care. These high-stakes decisions often challenge patients and oncologists in addressing patient values, a crucial component of SDM. We hypothesized that the intervention would improve oncologist-patient communication, specifically SDM application, and (consequently) reduce patient decisional conflict.

Methods: In this prospective, multicentre pre-post clinical study, patients completed two surveys, and their recorded consultations on early phase clinical trials and palliative care were assessed by independent coders. Pre-intervention patients received usual care, while post-intervention patients used the OnVaCT. Oncologists underwent communication training between study phases. Endpoints included decisional conflict (primary), the extent to which oncologists, patients and relatives participate in SDM, consultation length, and patient decisions (secondary).

Results: Decisional conflict ($p = 0.394$) did not differ between pre-test ($n = 116$, $M = 30.0$, SD = 16.9) and post-test ($n = 99$, $M = 29.4$, SD = 15.2). Oncologists significantly increased their SDM application post-intervention ($p < 0.001$; $n = 129$, $M = 38.5$, SD = 12.6) compared to pre-intervention ($n = 163$, $M = 28.8$, SD = 9.2), particularly when the OnVaCT was discussed. Other outcomes, including consultation length, remained stable.

Conclusions: The OnVaCT intervention enhanced SDM and supported value-based discussions, without prolonging consultations. Further research should explore whether additional implementation efforts could reduce decisional conflict and the

intervention's potential impact on other patient-centred outcomes. Some decisions, however, may inherently involve unresolved conflict.

1 | Background

Every year, millions of people are diagnosed with and/or die of cancer [1]. Between diagnosis and death, patients can undergo an increasing number of therapies, but often exhaust standard treatment options at some point. Palliative care services can still be used to prevent or relieve patients' suffering [2]. Sometimes, these patients may also choose to participate in early phase clinical trials. These trials are designed to test the safety of new medical compounds and are essential for the development of new, effective anti-cancer treatments. However, as information on the effectiveness of drugs used in early phase clinical trials is not yet available, there is no clear 'best' or 'worst' option for the patient. The decision to participate in a trial can thereby pose a dilemma for patients: what should they choose?

Well-balanced decision-making is essential to help patients spend their remaining time in accordance with their values and beliefs [3]. Therefore, shared decision-making (SDM) is widely recommended [4], as it helps patients make treatment decisions that are consistent with their personal values [5], and improves cognitive-affective patient outcomes [6]. This may be particularly important for complex decisions, such as participation in early phase clinical trials, which must be made in the absence of evidence of a new drug's efficacy. Leading SDM models advocate discussion of patient values and preferences [7, 8]. However, oncologists do not always address patients' values [9, 10], and patients experience difficulties in sharing them [11]. Consequently, patients may experience decisional conflict after deciding on potential early phase clinical trial participation [12]. Decisional conflict expresses patients' unresolved decisional needs (e.g. personal uncertainty and related deficits in knowledge, value clarification, and support) [13] and is often used to assess the quality of decision-making [14, 15]. Improving the decision-making process of patients with advanced cancer contributes to their health-related quality of life [16]. In the case of early phase clinical trials, the SDM process could be improved with interventions supporting the clarification and discussion of patients' personal values regarding trial participation and palliative care [17]. Whether this improves SDM and reduces patients' decisional conflict remains unstudied.

An intervention that aims to do this is the OnVaCT intervention, which consists of a narrative-based online value clarification tool (OnVaCT) for patients and communication training for oncologists. The intervention was systematically developed and pilot-tested [18] following the Medical Research Council (MRC) framework for complex interventions [19]. The current study aims to evaluate its impact. We hypothesized that the OnVaCT intervention would improve oncologist-patient communication, specifically the application of SDM, and reduce patient decisional conflict. In addition, we expected that the extent to which oncologists involved patients in SDM would mediate the effect of using the OnVaCT intervention on patients' decisional conflict. We did not necessarily expect the intervention to affect patients' decisions or consultation length.

2 | Methods

2.1 | Study Design

The OnVaCT project (Netherlands Trial Registry: NL7335) was a prospective, multicentre pre-post clinical study in patients referred for potential early phase clinical trial participation [17]. We applied a between-subjects design: patients included in the pre-intervention phase (i.e. before implementation of the OnVaCT intervention) functioned as control group receiving usual care, while patients in the post-intervention phase (i.e. after implementation) functioned as the intervention group and were asked to use the OnVaCT. Oncologists participated in the communication training between study phases. The Medical Ethics Committee of the Erasmus MC (Rotterdam, the Netherlands) approved the project proposal (MEC-2018-151), and the Erasmus MC, Netherlands Cancer Institute (Amsterdam, the Netherlands) and UMC Utrecht (Utrecht, the Netherlands) gave research governance approval. The CONsolidated Standards of Reporting Trials Statement extension for reporting Social and Psychological Intervention trials (CONSORT-SPI 2018) [20] were followed.

2.2 | Participants

Inclusion criteria were (1) diagnosed with advanced cancer; (2) aged $\geq$ 18 years; (3) sufficient command of the Dutch language; (4) eligible for first participation in an early phase clinical trial (i.e. phase I or I/II); and (5) written informed consent. Exclusion criteria were: (1) cognitive impairment according to the medical record; (2) no access to the internet; and (3) previous participation in the interview study of this project (N = 13) [21].

2.3 | The Intervention

The OnVaCT intervention [18, 22] was systematically developed following the MRC Framework for complex interventions [19], in co-creation with the end-users (i.e. patients and oncologists). The intervention consisted of two parts: the OnVaCT and a communication training. The patient-oriented OnVaCT (www.mijnwensenbijkanker.nl) was created by a professional company that specializes in interactive and engaging digital tools, such as serious games and experiential platforms. It features five characters (avatars)—hypothetical patients considering participation in early phase clinical trials. In the OnVaCT, patients are taken on a 'virtual walk' during which they can choose to walk with one or more characters. Each character can tell three narratives (stories) about their contemplations on early phase clinical trial participation and palliative care, based on different (sub)sets of values and targeted questions (e.g., 'How do you feel about that?') to make patients reflect on their own values ahead of the consultation. The narratives and values were derived from a prior systematic review [3] and interview study [21].

A psychologist with expertise in communication skills trainings provided the communication training to oncologists in three parts: (1) Web lecture: A 15-min video providing an overview on SDM in consultations about potential participation in early phase clinical trials; (2) Individual feedback: Oncologists assessed one of their own pre-intervention recordings using SDM steps (about an hour of preparation), followed by a 30-min personalized feedback session; and (3) Group training: A 2-h interactive session focussed on integrating the OnVaCT and discussing patient values within consultations, guided by SDM principles.

This structured approach ensured both patients and oncologists were effectively prepared to engage in SDM.

2.4 | Procedures

Figure 1 shows the data collection process. Due to the pre-post design, blinding participants was not part of the procedures. During the pre-intervention phase (i.e., usual care), patients who verbally consented to participate, received a link to the baseline questionnaire, starting with asking online consent. They were requested to complete it before their first consultation on participation in an early phase clinical trial. After signing written informed consent, patients' initial consultation was recorded to allow evaluation of the SDM process. Relatives were not consented separately as they were not required to actively participate in extra study procedures. However, they were given opportunities to object to being recorded—although they typically followed the patient's decision to participate in this study. A link to the final questionnaire was sent 3 weeks later. Data on patients' decision and medical status (e.g., WHO performance status) were collected afterwards from electronic patient records.

After completing the pre-intervention phase, the intervention was implemented and the communication training was delivered to 10 oncologists from the participating early phase clinical research units (Erasmus MC $N = 4$, Netherlands Cancer Institute $N = 5$, and UMC Utrecht $N = 1$), one of whom only participated post-intervention. Three additional oncologists only participated pre-intervention. Next, during the post-intervention phase, the procedures described above were repeated, with the difference that patients also received a link to the OnVaCT and related questions with their baseline questionnaire. They were

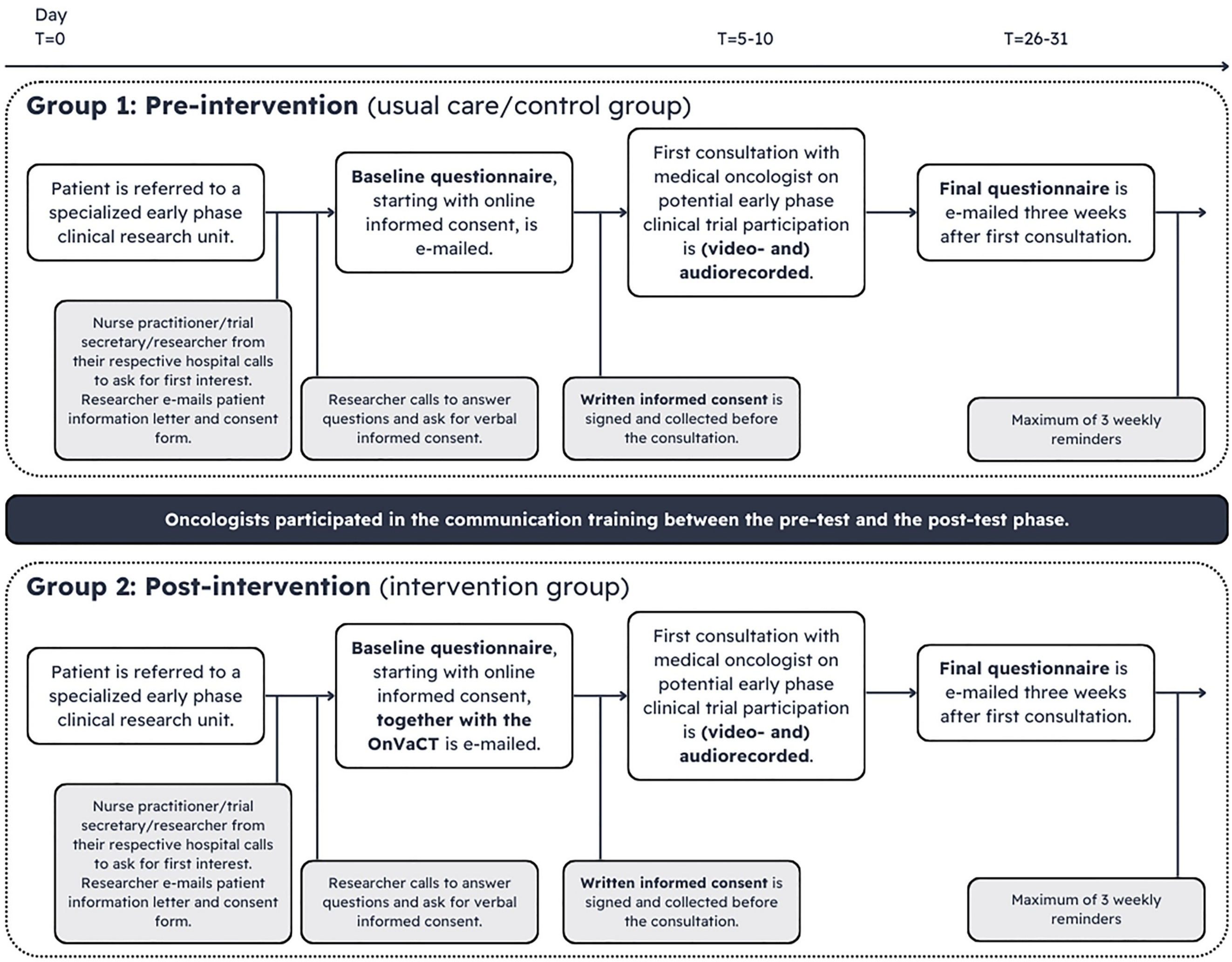

FIGURE 1 | Data collection procedures in the pre-intervention and post-intervention phase.

requested to use the OnVaCT before their first consultation on participation in an early phase clinical trial.

2.5 | Measurements and Outcomes

Supporting Information S1 describes all measurements. The baseline questionnaire assessed the validated control variables: health literacy [23], sense of hope [24], quality of life [25], and post-intervention also technology acceptance [26] and satisfaction with the tool [27]. This questionnaire also assessed the socio-demographics: age, gender, education level, nationality, living situation, and employment status. Post-intervention, patients' actual OnVaCT usage was tracked with Google Analytics. The primary and secondary outcomes are described consecutively below.

2.5.1 | Decisional Conflict

The final questionnaire assessed patients' decisional conflict (primary outcome) using the Decisional Conflict Scale (DCS) [13]. The DCS consists of 16 items on a 5-point Likert scale (0 = 'strongly agree'—4 = 'strongly disagree') within the Informed, Values clarity, Support, Uncertainty, and Effective decision subscales. Following the user manual, DCS scores were transformed to a 0-100 scale.

2.5.2 | SDM

To assess the SDM process (secondary outcomes), four independent observers encoded the recorded consultations using the adapted Observer OPTION-MCC [28]. Six behavioural competences for medical oncologists (i.e. Goal talk, Option talk: present options, Team talk, Option talk: discuss pros and cons, Decision talk: elicit preferences, and Decision talk: decide together) were assessed on a five-point Likert Scale (0 = 'the behaviour is not observed'—4 = 'the behaviour is observed and executed to a high standard'). The extent to which patients and relatives participated in these steps were also assessed on a five-point scale (0 = 'passive'—4 = 'very active'). Following OPTION-5 guidelines [29], the oncologists' SDM scores were transformed to a 0–100 score. To establish inter-observer reliability, every fourth recording was assigned to multiple observers. The majority of recordings was encoded blindly (see Supporting Information S1).

2.5.3 | Consultation Length

The consultation length (secondary outcome) was measured as the duration of the recording in minutes.

2.5.4 | Patients' Decisions on Trial Participation

Patients' decision on early phase clinical trial participation (i.e., decided to participate or not; secondary outcome) was retrieved from electronic patient records.

2.6 | Power Calculations

Assuming a mean DCS score of 27 (SD = 12) in the pre-intervention phase [30], we required a sample size of 276 patients (138 pre-intervention and post-intervention) to acquire an 80% power to detect an effect size of 0.30 (or absolute difference of 3.6) in DCS score with an alpha-level of 0.05 (one-sided) [17].

2.7 | Statistical Analysis

An intention-to-treat approach was applied, including post-intervention patients regardless of using the OnVaCT. For the SDM measurements and OnVaCT usage, all available data were used (i.e., not only patients who completed both questionnaires). Using IBM SPSS Statistics 28, descriptive statistics were generated for all variables. Using non-response analyses (i.e., Chi-square tests, Fisher's exact tests and a two-sided *t*-test), we checked for differences in socio-demographics between patients in the final analysis and those who dropped out after written informed consent. Cronbach's alphas were calculated to verify the internal reliability of baseline characteristics measured with multicomponent instruments, such as the primary outcome decisional conflict. For the SDM measurements, inter-observer agreement was assessed using intra-class correlation coefficient (ICC), summarized with Cronbach's alpha, with scores above 0.40, 0.60, and 0.80 respectively indicating fair, moderate, and substantial agreement.

Differences in the primary outcome decisional conflict between study phases were analysed with one-sided *t*-tests. For technology acceptance, satisfaction with the tool, and actual OnVaCT usage, only descriptive statistics could be provided. Differences between study phases for all other variables were analysed with Chi-square tests, Fisher's exact tests, two-sided *t*-tests and Mann-Whitney U-tests, where appropriate. Sensitivity analyses were performed with the blind-coded recordings for the SDM measurements. For the primary and secondary outcomes, we performed multivariable linear regression analyses (for decisional conflict, SDM measurements, and consultation length) and binary logistic regression analysis (for patients' decisions) to correct for possible imbalance between study phases, using socio-demographics, performance status, health literacy and sense of hope as covariates in case of liberally significant differences ($p \leq 0.15$) [31].

Eventually, we planned to perform a mediation analysis with decisional conflict as dependent variable, the extent to which oncologists involve patients in SDM as mediator, and the intervention/study phase as independent variable. Again, socio-demographics, performance status, health literacy and sense of hope could be used as covariates in case of liberal significance ($p \leq 0.15$) [31].

2.7.1 | Post-Hoc Analyses

Explorative post-hoc analyses were performed for SDM measurements and decisional conflict. Using one-sided *t*-tests or Mann-Whitney U-tests, per-protocol post-hoc analyses were performed to compare the results of pre-intervention patients to post-intervention patients who used the OnVaCT (based on Google Analytics) and in whose consultations the OnVaCT was explicitly mentioned. Similarly, we compared the results of post-intervention patients in whose consultations the OnVaCT was mentioned to those in which it was not.

3 | Results

3.1 | Patient Inclusion and Characteristics

Patients referred to the participating early phase clinical research units between February 18, 2019 and December 18, 2020 were approached for the pre-intervention phase [12]. Between January 26, 2021 and August 31, 2022, patients were approached for the post-intervention phase. Between these phases, the OnVaCT intervention was implemented. Figure 2 provides the inclusion flowchart. In total, 552 patients (302 pre-intervention vs. 250 post-intervention) were approached, of whom 342 gave written informed consent (193 vs. 149). The final analysis on decisional conflict included 215 patients who completed both questionnaires (116 vs. 99). For the analyses of SDM measurements, 292 recordings (163 vs. 129) were included. Patients in the final analysis (N = 215) and those who dropped out after giving written informed consent (N = 127) did not significantly differ in terms of gender or age, but did in education level ($\chi^2(2)$ = 6.353, p = 0.042). Compared to the final sample, patients who dropped out relatively more often had a low (40.2% vs. 27.4%) and less often a middle education level (24.4% vs. 33.0%), whereas high education levels were similar (35.4% vs. 39.5%). The study phases did not significantly differ in patient demographics (Table 1): most patients were male (67.2% pre-intervention vs. 63.6% post-intervention), had a Dutch nationality (99.1% vs. 98.0%), lived with a partner (62.9% vs. 60.6%) and were unemployed (56.9% vs. 56.6%).

The baseline measurements health literacy (α = 0.672), sense of hope (α = 0.817), technology acceptance (α = 0.924) and satisfaction with the tool (α = 0.911) had an adequate to high *internal* reliability. Pre-intervention patients (M = 36.8, SD = 4.9) had a significantly lower sense of hope than post-intervention patients (M = 38.2, SD = 4.5; $t(213)$ = −2.131, p = 0.034). The other baseline measurements (Table 1) showed no significant differences.

Regarding OnVaCT usage (Table 1), Google Analytics data recognized 124 unique patient codes (of 168 patients who received one). On average, post-intervention patients who visited the OnVaCT did so 1–2 times, spent almost 20 min with it and watched around 7 narratives per visit, divided over two to three characters. The most frequently chosen narratives (besides the introductory stories) concerned patients' relation with others, dependence, and choosing trial participation. Overall, post-intervention patients were accepting of technology (M = 5.1, SD = 0.9) and satisfied with the OnVaCT (M = 5.2, SD = 0.8).

3.2 | Decisional Conflict

The primary outcome decisional conflict (α = 0.895) had a high internal reliability. Table 2 shows that mean decisional conflict pre-intervention was 30.0 (SD = 16.9) and post-intervention 29.4 (SD = 15.2). A one-sided t-test ($t(213)$ = 0.269, p = 0.394) and regression analysis corrected for possible imbalances between study phases (Table 3) found no significant relation between the intervention and decisional conflict. A per-protocol post-hoc analysis ($t(161)$ = 1.752, p = 0.041) showed that pre-intervention patients (M = 24.2, SD = 18.1) experienced significantly more decisional conflict on the 'Support' subscale compared to post-intervention patients who used the OnVaCT and in whose consultation this was mentioned (N = 37, M = 19.0, SD = 15.1). Other per-protocol and explorative post-hoc analyses revealed no significant differences (Supporting Information S2 and S3).

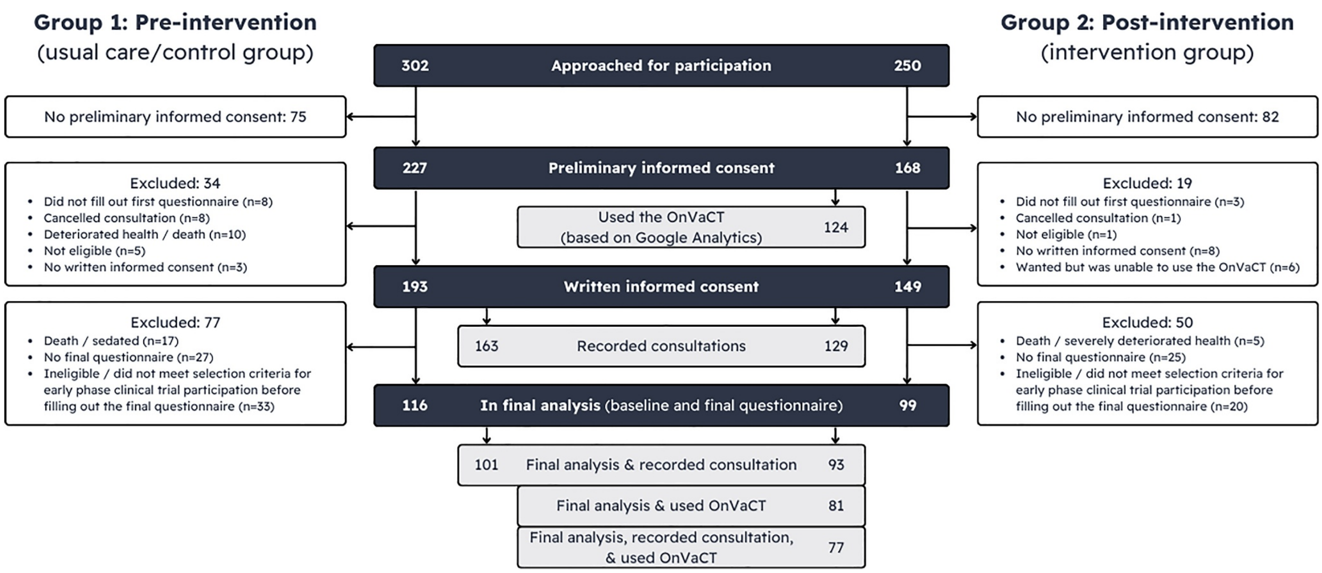

FIGURE 2 | Flowchart for patient inclusion in the pre-intervention and post-intervention phase.

TABLE 1 | Patient characteristics and baseline measurements for the pre-intervention and post-intervention groups.

	Pre-intervention[a] (N = 116)	Post-intervention (N = 99)	p-value
Gender, N (%)			0.579[f]
Female	38 (32.8)	36 (36.4)	
Male	78 (67.2)	63 (63.6)	
Age, M (SD)	62.5 (8.8)	61.6 (9.7)	0.456[e]
Education level, N (%)			0.081[f]
Low (no education to lowest level of secondary education)	29 (25.0)	30 (30.3)	
Middle (senior general secondary and pre-university education)	46 (39.7)	25 (25.3)	
High (higher vocational education and university)	41 (35.3)	44 (44.4)	
Nationality, N (%)			0.596[c]
Dutch	115 (99.1)	97 (98.0)	
Other	1 (0.9)	2 (2.0)	
Living situation, N (%)			0.556[c]
Alone	12 (10.3)	7 (7.1)	
With partner	73 (62.9)	60 (60.6)	
With partner and child(ren)	27 (23.3)	30 (30.3)	
With child(ren) or other relative(s)	4 (3.4)	2 (2.0)	
Working situation, N (%)			0.591[f]
Paid job	32 (27.6)	23 (23.2)	
No job (anymore)	66 (56.9)	56 (56.6)	
In health insurance act	10 (8.6)	14 (14.1)	
Other (e.g. voluntary work)	8 (6.9)	6 (6.1)	
Hospital, N (%)			0.215[f]
Erasmus MC	84 (72.4)	62 (62.6)	
Netherlands cancer Institute	23 (19.8)	23 (23.2)	
UMC Utrecht	9 (7.8)	14 (14.1)	
WHO performance status at initial consultation, N (%)			0.218[c]
0	27 (23.3)	21 (21.2)	
1	74 (63.8)	57 (57.6)	
2 or 3	6 (5.2)	4 (4.0)	
Missing/unknown	9 (7.8)	17 (17.2)	
Primary diagnosis, N (%)			0.338[c]
Colorectal/anal cancer	35 (30.2)	30 (30.3)	
Oesophageal/stomach cancer	11 (9.5)	12 (12.1)	
Hepatobiliary/pancreatic cancer	20 (17.2)	10 (10.1)	
Gynaecological cancer	6 (5.2)	5 (5.1)	
Lung cancer/mesothelioma	8 (6.9)	8 (8.1)	
Genito-/Urinary tract cancer	26 (22.4)	18 (18.2)	
Breast cancer	3 (2.6)	3 (3.0)	
Melanoma/skin cancer	3 (2.6)	1 (1.0)	
Other	4 (3.4)	12 (12.1)	
Metastases, N (%)			0.292[c]
Yes	110 (94.8)	97 (98.0)	
No	6 (5.2)	2 (2.0)	

(Continues)

TABLE 1 | (Continued)

	Pre-intervention[a] (N = 116)	Post-intervention (N = 99)	p-value
Missing		4	
Number of previous lines of therapy, M (SD)	2.6 (1.6)	2.7 (1.7)	0.259[e]
Missing/unknown, N (%)	6 (5.2)	9 (9.1)	
Participated in another (non-early phase) clinical trial, N (%)			0.501[f]
Yes	26 (22.4)	19 (19.2)	
No	90 (77.6)	79 (29.8)	
Unknown		1 (1.0)	
Quality of life, M (SD)			
Global health status	67.4 (18.4)	69.8 (18.8)	0.347[e]
Health literacy, M (Q1-Q3)	4.7 (4.3–5.0)	4.7 (4.3–5.0)	0.121[d]
Sense of hope, M (SD)	36.8 (4.9)	38.2 (4.5)	0.034[e]
Actual OnVaCT usage,[b] N	N/A		N/A
Unique patient codes		124	
Number of website visits/homepage views		199	
Average time spent on the website (mm:ss)		19:14	
Select avatar/player (total number of times that an avatar was selected)			
Male		105	
Female		79	
Select character (total number of times that a character was selected)			
Character 1: Wouter (introduction/coach)		73	
Character 2: Hubert		85	
Character 3: Wim		75	
Character 4: Claudia		70	
Character 5: Jordy		68	
Character 6: Yalda		66	
Average number of characters chosen per website visit		2.2	
Select story (total number of times that a story was selected)			
About the importance of walking (introduction/coach)		265	
About how walking works (introduction/coach)		226	
About relations with others		167	
About dependence		106	
About choosing participation in a clinical trial		79	
About still enjoying		68	
About making choices		61	
About recording things		60	
About maintaining hope		55	
About spending time		54	
About my body		51	
About being ill		50	
About distraction		47	
About faith and spirituality		36	
Average number of stories chosen per website visit		6.7	

(Continues)

TABLE 1 | (Continued)

	Pre-intervention[a] (N = 116)	Post-intervention (N = 99)	p-value
Technology acceptance, M (SD)	N/A		N/A
Performance expectancy		4.9 (1.2)	
Effort expectancy		5.4 (1.0)	
Social influence		4.1 (1.5)	
Facilitating conditions		5.9 (1.0)	
Behavioural intention		5.1 (1.3)	
Total technology acceptance		5.1 (0.9)	
Missing, N (%)		2 (2.0)	
Satisfaction with the tool, M (SD)	N/A		N/A
Satisfaction with attractiveness		5.6 (0.8)	
Satisfaction with comprehensibility		6.1 (0.8)	
Satisfaction with emotional support		4.2 (1.3)	
Total satisfaction with the tool		5.2 (0.8)	
Missing, N (%)		2 (2.0)	

[a]Pre-intervention patient characteristics were previously reported elsewhere [12].
[b]Patients received the OnVaCT with a unique (anonymised) code to be able to distinguish patient usage from 'other' usage of the OnVaCT. The data reported in this table include those of 124 unique codes that could be identified in Google Analytics, that is without distinguishing between patients in the final analysis from those who dropped out. The number of times that for example the OnVaCT was viewed or stories were chosen can differ from the number of patients, indicating for example that not all patients chose an option/story, or that at least some patients chose an option/story more than once. It is also possible that some patients shared their unique link with for example a close relative who used the tool with the unique code.
[c]p-value from Fisher's exact test.
[d]p-value from Mann-Whitney U-test.
[e]p-value from two-sided t-test.
[f]p-value from chi-square test.

3.3 | SDM

Based on 78 double-coded recordings, the total scores of participation in SDM for oncologists (α = 0.834), patients (α = 0.811) and relatives (α = 0.889) had a substantial internal reliability. A two-sided t-test (Table 2, $t(228.582) = -7.332$, $p < 0.001$) showed that the extent to which oncologists involved patients in SDM significantly increased (pre-intervention: M= 28.8, SD = 9.2 vs. post-intervention: M = 38.5, SD = 12.6). A sensitivity analysis using the 219 blind-coded recordings only ($t(211.507) = -5.971$, $p < 0.001$), regression analyses (Table 3), and per-protocol post-hoc analyses (Supporting Information S2) confirmed this significant relationship between the intervention and (all steps of) SDM. Moreover, oncologists involved post-intervention patients significantly more in SDM when the OnVaCT was explicitly mentioned (N = 80) compared to when it was not (N = 49; $t(127) = -2.398$, p = 0.009); particularly, the steps 'Option talk: present options', 'Decision talk: elicit preferences', and 'Decision talk: decide together' showed differences (Supporting Information S3).

Pre-intervention (M = 1.7, SD = 0.6) and post-intervention (M = 1.7, SD = 0.5) patients both showed 'responsive' to 'very responsive' participation in SDM. Pre-intervention (M = 0.8, SD = 0.6) and post-intervention (M = 0.8, SD = 0.6) relatives showed 'passive' to 'responsive' participation in SDM. Two-sided t-tests and Mann-Whitney U-tests (Table 2), regression analyses (Table 3), and per-protocol and explorative post-hoc analyses (Supporting Information S2 and S3) revealed no significant differences in the extent to which patients and relatives participated in SDM.

3.4 | Consultation Length

A two-sided t-test ($t(199) = -0.799$, p = 0.425, Table 2) and regression analysis (Table 3) showed no significant differences in consultation length (pre-intervention: M = 36.8, SD = 11.3 vs. post-intervention: M = 38.2, SD = 14.3).

3.5 | Patients' Decisions on Trial Participation

Most pre-intervention (66.4%) and post-intervention patients (73.7%) decided to further consider participation in early phase clinical trials. A Chi-square test ($\chi^2(1) = 1.371$, p = 0.242, Table 2), and binary logistic regression analysis (Table 3) showed no significant differences in patients' decisions.

3.6 | Mediation Analysis

The intervention/study phase did not affect decisional conflict, and therefore the assumptions for performing mediation analyses were not met [32] (see Supporting Information S1) and no mediation occurred by the hypothesized mediator (SDM by oncologists; F(15,177) = 0.655, p = 0.826).

TABLE 2 | Pre-intervention and post-intervention results.

	Pre-intervention (*N* = 163) *M* (SD or Q1-Q3)	Post-intervention (*N* = 129) *M* (SD or Q1-Q3)	*p*-value	B (95%CI)
Extent to which *oncologists* involve patients in SDM				
1. Goal talk	1.0 (0.7)	1.5 (1.1)	< 0.001[c]	(−0.751, −0.322)
2. Option talk: present options	1.1 (0.7)	1.5 (0.8)	< 0.001[c]	(−0.558, −0.195)
3. Team talk: form partnership	0.3 (0.6)	0.7 (0.8)	< 0.001[c]	(−0.516, −0.161)
4. Option talk: discuss pros and cons	1.8 (0.7)	2.1 (0.7)	0.002[c]	(−0.442, −0.099)
5. Decision talk: elicit preferences	1.4 (0.7)	2.1 (0.9)	< 0.001[c]	(−0.933, −0.546)
6. Decision talk: decide together	1.5 (0.6)	1.7 (0.6)	0.009[c]	(−0.347, −0.050)
Total OPTION-MCC score	1.2 (0.4)	1.6 (0.5)	< 0.001[c]	(−0.517, −0.301)
Total transformed OPTION-MCC score	28.7 (9.1)	38.5 (12.6)	< 0.001[c]	(−12.421, −7.228)
Extent to which *patients* participate in SDM				
1. Goal talk	1.9 (1.4)	2.0 (1.3)	0.366[c]	(−0.458, 0.169)
2. Option talk: present options	1.0 (1.3)	1.0 (1.3)	0.943[c]	(−0.283, 0.304)
3. Team talk: form partnership	0.2 (0.5)	0.2 (0.5)	0.942[c]	(−0.116, 0.125)
4. Option talk: discuss pros and cons	2.6 (1.1)	2.6 (1.1)	0.995[c]	(−0.257, 0.258)
5. Decision talk: elicit preferences	2.6 (1.3)	2.7 (1.1)	0.396[c]	(−0.407, 0.162)
6. Decision talk: decide together	1.7 (1.3)	1.8 (1.2)	0.705[c]	(−0.348, 0.235)
Total OPTION-MCC score	1.7 (0.6)	1.7 (0.5)	0.459[c]	(−0.187, 0.085)
Extent to which *relatives* participate in SDM[a]				
1. Goal talk	0 (0–1)	0 (0–1)	0.716[d]	(−0.172, 0.257)[c]
2. Option talk: present options	0 (0–0)	0 (0–0)	0.294[d]	(−0.106, 0.300)[c]
3. Team talk: form partnership	0 (0–0)	0 (0–0)	0.470[d]	(−0.079, 0.024)[c]
4. Option talk: discuss pros and cons	3 (1–3)	2 (1–3)	0.238[d]	(−0.130, 0.522)[c]
5. Decision talk: elicit preferences	1 (0–2)	1 (0–2)	0.470[d]	(−0.386, 0.202)[c]
6. Decision talk: decide together	0 (0–1)	1 (0–1)	0.327[d]	(−0.375, 0.123)[c]
Total OPTION-MCC score	0.8 (0.5–1.2)	0.8 (0.3–1.3)	0.878[d]	(−0.124, 0.156)[c]

	Pre-intervention[b] (*N* = 116) *M* (*SD*) or *N* (%)	Post-intervention (*N* = 99) *M* (*SD*) or *N* (%)	*p*-value
Consultation length in minutes	36.8 (11.3)	38.2 (14.3)	0.425[c]
Decision regarding trial participation			0.242[e]
Decided to further consider participation	77 (66.4)	73 (73.7)	
Decided to not further consider participation (and not to participate)	39 (33.6)	26 (26.3)	
Decisional conflict (DCS)			
Informed subscale	31.5 (21.3)	29.1 (18.4)	0.190[c]
Values clarity subscale	36.6 (20.6)	36.2 (21.0)	0.438[c]
Support subscale	24.2 (18.1)	23.3 (16.9)	0.355[c]
Uncertainty subscale	36.6 (24.9)	35.9 (23.6)	0.426[c]
Effective decision making subscale	23.3 (20.4)	24.2 (18.7)	0.369[c]
Total decisional conflict	30.0 (16.9)	29.4 (15.2)	0.394[c]

[a]There was no relative present in some consultations in the pre-intervention (n = 10) and the post-intervention phase (n = 7).
[b]Pre-intervention patient measurements (except for SDM scores) were previously reported elsewhere [12].
[c]*p*-value (and/or B-values) from *t*-test (one-sided for DCS, two-sided for other outcomes).
[d]*p*-value from Mann-Whitney *U*-test.
[e]*p*-value from Chi-square test.

TABLE 3 | Regression analyses corrected for education level, health literacy[a] and sense of hope.

Extent to which oncologists involve patients in SDM	**F**	**df**	**Adjusted R^2**	***p*-value**
Multivariable regression model statistics	10.554	(4189)	0.165	< 0.001
	b	**95% CI**	***β***	**p-value**
Intervention/study period	9.703	(6.485, 12.922)	0.400	< 0.001
Education level (ref. category: low education level)				
Middle education level	−3.516	(−7.654, 0.621)	−0.137	0.095
High education level	−2.715	(−6.653, 1.222)	−0.110	0.175
Sense of hope	−0.133	(−0.467, 0.201)	−0.052	0.433
Constant	36.229	(23.278, 49.181)		< 0.001
Extent to which patients participate in SDM	***F***	***df***	***Adjusted R^2***	***p-value***
Multivariable regression model statistics	5.566	(4189)	0.086	< 0.001
	b	**95% CI**	***β***	**p-value**
Intervention/study period	0.034	(−0.133, 0.202)	0.028	0.686
Education level (ref. category: low education level)				
Middle education level	0.014	(−0.202, 0.229)	0.011	0.900
High education level	0.405	(0.200, 0.610)	0.328	< 0.001
Sense of hope	−0.004	(−0.022, 0.013)	−0.035	0.618
Constant	1.659	(0.985, 2.334)		< 0.001
Extent to which relatives participate in SDM[b]	***F***	***df***	***Adjusted R^2***	***p-value***
Multivariable regression model statistics	2.258	(4160)	0.030	0.065
	b	**95% CI**	***β***	**p-value**
Intervention/study period	−0.049	(−0.136, 0.038)	−0.087	0.268
Education level (ref. category: low education level)				
Middle education level	−0.031	(−0.142, 0.080)	−0.053	0.578
High education level	0.067	(−0.039, 0.173)	0.118	0.212
Sense of hope	0.009	(0.000, 0.018)	0.156	0.049
Constant	−0.439	(−0.790, −0.089)		0.014
Consultation length	***F***	***df***	***Adjusted R^2***	***p-value***
Multivariable regression model statistics	1.570	(4196)	0.011	0.184
	b	**95% CI**	***β***	**p-value**
Intervention/study period	1.970	(−1.653, 5.593)	0.077	0.285
Education level (ref. category: low education level)				
Middle education level	1.310	(−3.406, 6.025)	0.048	0.584
High education level	2.878	(−1.549, 7.305)	0.111	0.201
Sense of hope	−0.384	(−0.764, −0.004)	−0.142	0.048
Constant	49.317	(34.597, 64.037)		< 0.001
Decision regarding trial participation (0 = decided not to participate, 1 = decided to participate)	***χ^2***	***df***	***Cox & Snell R^2***	***p-value***
Binary logistic regression model statistics	6.458	4	0.030	0.167
	b	**Exp(B)**	**95% CI**	**p-value**
Intervention/study period	0.352	1.422	(0.773, 2.617)	0.258
Education level (ref. category: low education level)				
Middle education level	0.672	1.958	(0.908, 4.224)	0.087
High education level	0.350	1.419	(0.696, (2.892)	0.336
Sense of hope	0.050	1.052	(0.986, 1.121)	0.123
Constant	−1.549	0.213		0.213

TABLE 3 (Continued)

Decisional conflict	*F*	*df*	*Adjusted R^2*	*p-value*
Multivariable regression model statistics	4.830	(4210)	0.067	< 0.001
	b	**95% CI**	**β**	**p-value**
Intervention/study period	0.275	(−4.003, 4.554)	0.009	0.899
Education level (ref. category: low education level)				
Middle education level	−4.684	(−10.133, 0.764)	−0.137	0.092
High education level	−2.837	(−8.029, 2.355)	−0.086	0.283
Sense of hope	−0.940	(−1.389, −0.491)	−0.276	< 0.001
Constant	67.502	(50.230, 84.774)		< 0.001

[a]We do not report health literacy as a covariate for the regression analyses because this variable was not normally distributed, nor did it become normally distributed after diverse transformations (i.e., inverted, squared, log-transformed). However, as a check, we repeated the regression analyses with health literacy (and the transformation that best resembled a normal distribution) as a covariate. In these analyses, patients' health literacy was only significantly related to two outcomes, that is the extent to which patients and relatives participated in SDM. The other outcomes were not significantly related to health literacy. The inclusion of health literacy in the regression analyses did not lead to significant changes for the relations between the intervention/study phase and the outcomes.

[b]The extent to which relatives participate in SDM (on a scale of 0–4) was not normally, but log-normally distributed. Therefore, the regression analysis was performed with the log-transformed scale.

4 | Discussion

This study aimed to evaluate the OnVaCT intervention's impact on SDM for potential early phase clinical trial participation. The intervention did not affect patients' decisional conflict. However, it improved oncologist-patient communication by significantly increasing the extent to which oncologists involved patients in SDM. Other outcomes remained stable: patients and relatives did not participate more/less actively in SDM, consultations were not prolonged, and most patients decided to further consider trial participation.

While clarifying and discussing patient values is important for SDM, this is often challenging for patients and oncologists [9–11], especially given the complexities surrounding early phase clinical trial participation and palliative care. Importantly, the OnVaCT intervention successfully increased the extent to which oncologists involved patients significantly more in all steps of SDM (28.8 pre-intervention vs. 38.5 post-intervention), including the discussion of patient goals and preferences, and especially when the OnVaCT was mentioned. These effects are remarkably high, even compared to other interventions aimed at improving SDM [33] and specifically for advanced cancer consultations [34]. Possibly, aligned with the communication training, discussing the OnVaCT helped oncologists to address the specific SDM steps. Moreover, similar to a previous meta-analysis [35], the OnVaCT intervention showed that better SDM did not increase oncologists' workload in terms of consultation length. These SDM improvements are especially meaningful in light of developments in national legislations and policies, which increasingly link SDM to informed consent [36, 37]. We therefore conclude that the intervention seems meaningful.

Nevertheless, neither the intervention nor the SDM improvements were found to reduce the primary outcome decisional conflict. The DCS levels in the current study (30.0 pre-intervention vs. 29.4 post-intervention) are consistent with those reported for standard cancer treatment decisions (around 28 [14]) and phase I clinical trial participation (26 for trial acceptors vs. 34 for decliners [30]), but are lower than those associated with end-of-life or palliative care decisions (45 [14]). This difference may relate to the composition of our study population: most patients opted to further consider trial participation, in contrast to generally lower enrolment rates in clinical cancer trials [38]. Given that decisional conflict is considered clinically elevated at levels above 25 [13], the DCS scores pre- and post-intervention suggest that decision-making for participation in early phase clinical trials remains challenging, albeit perhaps less difficult than other end-of-life decisions. The finding that decisional conflict was not reduced by the intervention nor SDM improvements could be explained in several ways.

Firstly, decisional conflict may be difficult to reduce in highly uncertain and complex decisions. While the intervention supported patients to express their values, and oncologists to discuss them, the external complexities of advanced cancer decisions remained. Despite our expectations, the 'values clarity' subscale remained rather high, possibly due to patients facing various undesirable options, leading to 'moral residue' [39] (e.g., ongoing doubts). This inner turmoil likely persisted despite improved SDM and might explain why decisional conflict is generally higher in end-of-life decisions than standard cancer treatment decisions [14]. Additionally, although we previously associated a higher sense of hope with less decisional conflict [12], a more recent review [40] suggests hope can also increase worries or disappointment (e.g., about trials' uncertain outcomes). This may have contributed to inner turmoil, especially among post-intervention patients. However, regression analyses correcting for hope still showed no effect of the intervention on decisional conflict. Moreover, no interventions have yet reduced decisional conflict in such highly complex and uncertain contexts. Future research should evaluate the suitability of decisional conflict in these contexts.

Secondly, the intervention may have been insufficiently implemented. While tracking data indicated that over 80% of post-intervention patients used the OnVaCT (see Figure 2), some patients mentioned not using it, which could not fully be verified due to privacy regulations. Additionally, the intervention was not mentioned in almost 40% of post-intervention consultations, despite existing evidence that discussing interventions improves outcomes [41]. Remarkably, a post-hoc analysis revealed that when the OnVaCT was used and mentioned, patients experienced less decisional conflict related to support and more SDM occurred, highlighting the importance of prompts in activating behaviour for both patients and clinicians. While the OnVaCT intervention was designed to activate patients and prompt oncologists to engage in SDM [18], further efforts to encourage discussion of the intervention may further reduce decisional conflict. It remains unclear whether the OnVaCT, the training, or both were the 'active ingredients'. A review of interventions in advanced cancer care suggests that at least a provider component should be included to improve SDM [34], whereas evidence from the systematic development [18] and a review on question prompt lists [42] support a combined approach.

Thirdly, the intervention may not have affected patients (outcomes). This study was underpowered due to notably larger standard deviations than anticipated with our power analysis [12] based on a previous study [30]. However, even with many more patients (declining ethical and practical considerations to include them), the difference in decisional conflict would likely not have been statistically significant nor clinically relevant. Interestingly, SDM participation by patients and relatives also remained stable, possibly due to oncologists' increased SDM efforts which enabled post-intervention patients to engage in responding to *questions* rather than to just *information*. Still, the nature of patients' responses might have changed, although the current scoring system did not assess this. A qualitative analysis suggests post-intervention patients discussed more values in context with each other [43]. Additionally, some patients and oncologists described the OnVaCT as emotionally supportive by showing patients they were not alone. Indeed, loneliness may negatively correlate with perceived social support [44], which contributes to better quality of life in patients with advanced cancer [45]. Feeling heard and understood could also address patients' psychological needs, potentially reducing distress, depression, and anxiety [46]. Thus, while the intervention may not have reduced decisional conflict, it may have improved patients' emotional well-being or perceived social support. Future research should consider these broader psychosocial outcomes, using measures such as anxiety, depression, Sinclair Compassion index, and perceived social support, to better capture the potential impact of such interventions.

4.1 | Limitations

In addition to the considerations addressed above, it should be noted that it is unclear to what extent the findings of this study can be generalized to the entire population of patients with advanced cancer who are eligible for participation in early phase clinical trials. For example, our study sample consisted of patients with relatively high education levels and health literacy compared to the entire Dutch population [47], and relatively many patients with low education level dropped out. Importantly, patients with high health literacy (which is related to high education [48]) are generally better able to participate in SDM [49], and less likely to regret their chosen treatment [50]. Yet, in contrast to what this suggests, patients in this study did not actively participate in SDM, even though SDM is preferred by most patients with cancer [51] and those facing palliative care decisions [52]. It is possible that patients were already quite self-conscious about the often conflicting considerations involved in deciding to participate in an early phase clinical trial (or not)—which might also explain why the intervention did not decrease decisional conflict. Furthermore, this study did not assess other patient-related characteristics (e.g. emotions or relationship building) that may have affected patient involvement in SDM [53]. It thus remains necessary to clarify individual patients' preferences for participating in SDM [54].

4.2 | Clinical Implications

With national legislations and policies increasingly connecting SDM to informed consent [36, 37], improving communication and SDM is of crucial importance to clinical practice. Our results suggest that the OnVaCT intervention could play an important role to achieve this for the context of contemplating participation in early phase clinical trials and/or palliative care. While most of the existing communication training materials have been designed to support professionals with SDM for standard treatment decisions, the decision to participate in early phase clinical trials poses fundamentally different challenges, as argued for example in this paper's introduction. The OnVaCT intervention was specifically designed for this context and could be integrated in the education of oncological specializations, such as oncologists-in-training or research nurses focussing on early phase clinical trials.

5 | Conclusion

To conclude, the OnVaCT intervention improved the extent to which oncologists involved patients in SDM, without prolonging consultations and especially when the intervention was used and mentioned. This illustrates the intervention's ability to improve SDM for potential early phase clinical trial participation and palliative care. Future research could explore whether additional implementation efforts, for instance by supporting active discussion of the intervention, could help to reduce decisional conflict. Additionally, we recommend considering other clinically relevant and patient-centred outcomes (e.g., emotional well-being and social support) to evaluate the intervention, as some decisions may simply never be made without conflict.

Author Contributions

C.C.D.v.d.R. acquired funding for the entire study project. C.C.D.v.d.R., J.C.M.v.W., M.J.A.d.J., M.P.L., E.O.-d.H., J.H., J.v.G. and L.G.G.v.L. conceptualized and designed the study. L.G.G.v.L., M.v.d.H., M.v.M., and E.H.G. contributed to the data collection. L.G.G.v.L. and E.O.-d.H. performed the statistical analysis, with advice from J.C.M.v.W., M.J.A.d.J. and C.C.D.v.d.R. All authors reviewed early versions and approved the final manuscript.

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Conflicts of Interest

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Data Availability Statement

Not all data presented in this study are publicly available due to privacy and ethical considerations. De-identified individual-level patient data will be made available through DANS upon publication.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.